# CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 50-775

**CHEMISTRY REVIEW(S)** 

# DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS Review of Chemistry, Manufacturing, and Controls

### NDA #: 50-775 CHEM.REVIEW #: 3 REVIEW DATE: 03-Mar-00

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	30-May-99	04-May-99	05-May-99
Gen. corresponden			Info
(Review document			
AMENDMENT/BC			07-Dec-99
(Stability data u			
AMENDMENT/BC			
(Response to clar	ification/addi	itional inform	mation as per
1/20/00 telecon)			
AMENDMENT/BC			
(Response to draf		comments faxed	
AMENDMENT/BC			03-Mar-00
(Response to 3/2/	00 teleconfere	ence- faxed re	esponse reviewed)

NAME & ADDRESS OF APPLICANT: Abbott Laboratories
100 Abbott Park Road
Abbott Park IL 6064-3500

### DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN:
Biaxin® XL Filmtab®
Clarithromycin extended release tablets

NA

Code Names/#'s:
Chemical Type/

Therapeutic Class: 3S

# ANDA Suitability Petition/DESI/Patent Status: N/A [if applicable]

### PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Tablet

STRENGTHS: 500 mg

ROUTE OF ADMINISTRATION: Oral

DISPENSED: X Rx \_\_\_\_\_ OTC

# CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

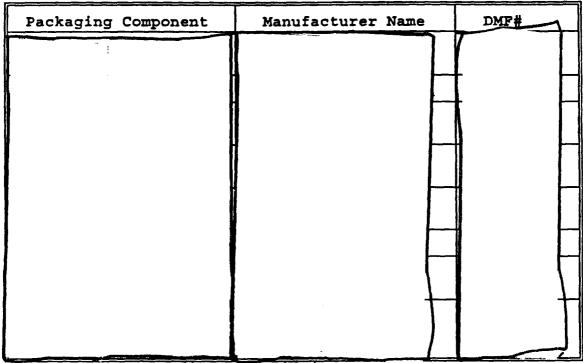
6-0-methylerythromycin. C<sub>38</sub>H<sub>69</sub>NO<sub>13</sub> 747.95

NDA 50-775 (Review 3)
Biaxin XL
(Clarythromycin extended release tablet)

### SUPPORTING DOCUMENTS

Letters of authorization for the following packaging DMFs provided in the application.

Table 1: Authorization to refer DMF



RELATED DOCUMENTS (if applicable):

The drug substance was approved under NDA 50-662.

### CONSULTS:

The following consultations were requested:

Table 2: Consultations

Consultation for:	Request Date	Status
Methods Validation	7/2699	Complete
Trademark Review	8/2/99	Complete
Facility Inspection	8/10/99	Complete

# REMARKS/COMMENTS:

Review 3 provides information sent to the applicant as an Attachment 1 with the action letter. Attachment 1 included the acceptance of 24 months shelf life, regulatory specifications and stability commitments for the drug

NDA 50-775 (Review 3) Biaxin XL

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(Clarythromycin extended release tablet)

product. Other pertinent information included in this review are approved manufacturing facilities for the drug product and drug substance and regulatory specifications for the drug substance. For all other information that was considered to be adequate, please see Review 1 and Review 2.

### CONCLUSIONS & RECOMMENDATIONS:

The application is approved for manufacturing and controls under 505(b) of the act.

Shrikant Pagay, Review Chemist

cc: Orig. NDA 50-775 (other NDA's may be included if

appropriate)

HFD-520/Division File

HFD-520/Pagay/date

HFD-520/Albuerne

HFD/520/Moledina

HFD-520/Ellis

HFD/520/Pelsor

HFD/520/Sun

HFD-520/Sheldon

HFD/520/Dong

HFD-520/Cintron

HFD-520/830 Katague

R/D Init by: SUPERVISOR/Team Leader

/S/3/3/cc

page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

# DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS Review of Chemistry, Manufacturing, and Controls

NDA #: 50-775 CHEM.REVIEW #: 2 REVIEW DATE: 28-Feb-00

SUBMISSION/TYPE D	OCUMENT	DATE	CDER	DATE	ASSIGNED	DATE
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ORIGINAL 30-May-99 04-May-99 05-May-99
AMENDMENT/BC 02-Dec-99 03-Dec-99 07-Dec-99
(Stability data update and clarification on DS facilities)
AMENDMENT/BC 04-Feb-00 07-Feb-00 15-Feb-00
(Response to clarification or additional information as per 1/20/00 telecon)
AMENDMENT/BC 25-Feb-00 28-Feb-00 28-Feb-00

AMENDMENT/BC 25-Feb-00 28-Feb-00 (Response to draft deficiency comments faxed on 2/11/00)

NAME & ADDRESS OF APPLICANT: Abbott Laboratories
100 Abbott Park Road

Abbott Park IL 6064-3500

DRUG PRODUCT NAME

<u>Proprietary:</u>
<u>Nonproprietary/USAN:</u>
Biaxin® XL Filmtab®
Clarithromycin extended

NA

release tablets

Code Names/#'s:

Chemical Type/

Therapeutic Class: 3S

ANDA Suitability Petition/DESI/Patent Status:

N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Tablet

STRENGTHS: 500 mg

ROUTE OF ADMINISTRATION: Oral

DISPENSED: X Rx \_\_\_\_ OTC

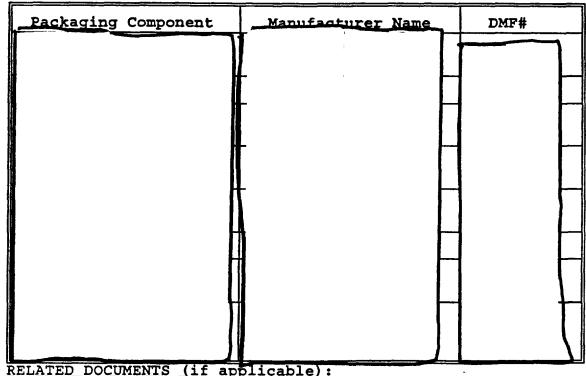
CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

6-0-methylerythromycin. C<sub>38</sub>H<sub>69</sub>NO<sub>13</sub> 747.95

### SUPPORTING DOCUMENTS

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#### CONSULTS:

The following consultations were requested: Table 2: Consultations

Consultation for:	Request Date	Status
Methods Validation	7/2699	Complete
Trademark Review	8/2/99	Complete
Facility Inspection	8/10/99	Complete

### REMARKS/COMMENTS:

All attachments referenced in this review without the original reference came from the Amendment dated 2/25/00.

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# CONCLUSIONS & RECOMMENDATIONS:

The application is approvable for manufacturing and controls under 505(b) of the act after the following concurrence from the applicant:

Acceptance of regulatory specifications and stability commitments.

The applicant will revise the drug product composition based on target quantities and adjust only the amount of for the potency of the drug substance lot used in manufacturing the drug product.

Applicant will monitor impurity profile of the first three production batches of the drug product and the related drug substance lot/s. The data will be submitted in the Annukal report at the end of stability studies.

> Shrikant Pagay, Review Chemist

cc: Orig. NDA 50-775 (other NDA's may be included if

appropriate)

HFD-520/Division File

HFD-520/Pagay/date

HFD-520/Albuerne

HFD/520/Moledina

HFD-520/Ellis

HFD/520/Pelsor

HFD/520/Sun

HFD-520/Sheldon

HFD/520/Dong

HFD-520/Cintron

HFD-520/830 Kataque

R/D Init by: SUPERVISOR/Team Leader 3/

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# DIVISION OF ANTI-INFECTIVE DRUG PRODUCTS Review of Chemistry, Manufacturing, and Controls

NDA #: 50-775 CHEM.REVIEW #: ONE REVIEW DATE: 08-Feb-00

SUBMISSION/TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE

ORIGINAL 30-May-99 04-May-99 05-May-99
AMENDMENT/BC 02-Dec-99 03-Dec-99 07-Dec-99
(Stability data update and clarification on DS facilities)

NAME & ADDRESS OF APPLICANT:

Abbott Laboratories

100 Abbott Park Road

Abbott Park IL 6064-3500

DRUG PRODUCT NAME

<u>Proprietary:</u>
<u>Nonproprietary/USAN:</u>
Biaxin® XL Filmtab®
Clarithromycin extended

release tablets

Code Names/#'s:

Chemical Type/

Therapeutic Class: 3S

ANDA Suitability Petition/DESI/Patent Status: N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: Anti-infective

DOSAGE FORM: Tablet

STRENGTHS: 500 mg

ROUTE OF ADMINISTRATION: Oral

DISPENSED: X Rx OTC

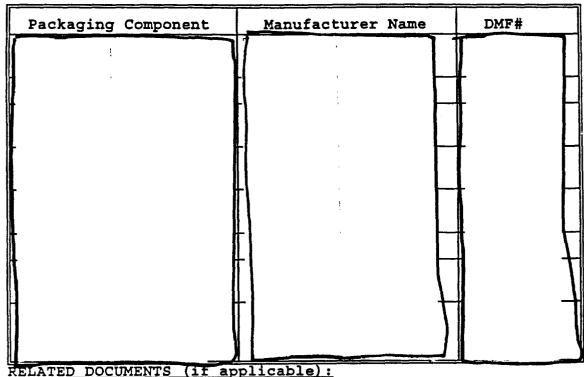
CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

6-0-methylerythromycin.  $C_{38}H_{69}NO_{13}$ 747.95 (Clarythromycin extended release tablet)

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Trademark Review	8/2/99	Complete
Facility Inspection	8/10/99	Complete

# REMARKS/COMMENTS:

NDA 50-775 Biaxin XL (Clarythromycin extended release tablet)

#### CONCLUSIONS & RECOMMENDATIONS:

The application is not approvable for manufacturing and controls under 505(b) of the act. The specific items which are not approvable are identified under the following heading: Drug Substance [synthesis and stability]; Drug product[components/composition, manufacturing and packaging, in-process controls, reprocessing, specifications and methods for drug product, container/closure, stability, investigational formulations, environmental assessment and labeling].

Shrikant Pagay, Review Chemist

cc: Orig. NDA 50-775 (other NDA's may be included if

appropriate)

HFD-520/Division File

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HFD/520/Dong

HFD-520/Cintron

HFD-520/830 Katague

R/D Init by: SUPERVISOR/Team Leader\_

15/ 2/9/00

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